

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/636,081 Examiner ANNETTE H. PARA	Applicant(s) GUPTA ET AL. Art Unit 1661
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–The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

THE REPLY FILED 05 April 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) The period for reply expires ____ months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

- (a) They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) They raise the issue of new matter (see NOTE below);
- (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. Applicant's reply has overcome the following rejection(s): _____.

6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: **1-13, 17-19, 21, 23-26**

Claim(s) withdrawn from consideration: _____

AFFIDAVIT OR OTHER EVIDENCE

8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fail to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____

13. Other: _____

/Annette H. Para/
Primary Examiner, Art Unit 1661

Response to Applicants' arguments

Applicants' arguments filed on 04/05/2010 have been fully considered, but they are not persuasive.

Applicants argue that Pullman does not teach or suggest cultivating pre-cotyledonary pine embryogenic cells for a period from one week to two weeks in, or on a synchronization medium, as recited in Claim 1 step (b). In contrast to the claimed invention, Pullman discloses a culturing step referred to as "singulation" for Douglas-fir. See Pullman et al. at Col. 8, lines 18-21.

Pullman et al. teaches the transfer of pre-cotyledonary Douglas-fir somatic embryos from a maintenance medium to a singulation medium for at least three weeks, followed by transfer to a development medium. As described in Examples 1-7, which are directed to methods for improving Douglas-fir embryo development, "late stage Douglas-fir proembryos were singulated in a three step liquid shake culture as outlined above." Example 2 at Col. 15, line 68, to Col. 16, line 2. As described in Example 1, a preferred schedule for the singulation step in Douglas-fir is "one week on a medium containing 10mg/L ABA, a second week on a medium containing 5mg/L ABA, and a third week on a medium also with 5mg/L ABA." Col. 15, lines 10-27.

It is further noted that Pullman does not teach or suggest the use of a medium that comprises maltose as the principal metabolizable sugar source, an absorbent composition and at least one synchronization agent selected from the group consisting of abscisic acid and a gibberellin, as claimed.

It is noted that Gupta does not teach or suggest cultivating pre-cotyledonary pine embryogenic cells for a period from one week to two weeks in, or on a synchronization medium, as recited in Claim 1 step (b). Rather, in contrast to the claimed invention, Gupta et al. teaches that Douglas-fir requires an intermediate singulation culturing step between early stage embryo growth and the final development stage due to the formation of tight clusters of embryos. As described in Gupta, singulation is carried out in a series of liquid shake cultures lacking auxins and cytokinins but which have exogenous abscisic acid added as a necessary new hormone. Gupta at Col. 8, lines 4-9.

'All of the claimed elements are not found in the cited references

In order to establish a prima facie case of obviousness, all of the claimed elements must be found in the prior art. See M.P.E.P. § 2143.

As discussed supra, both Pullman, and Gupta teach a culturing step referred to as "singulation" for Douglas-fir in which pre-cotyledonary Douglas-fir somatic embryos from a maintenance medium to a singulation medium for at least three weeks, followed by transfer to a development medium. Neither Pullman or Gupta teach or provide any suggestion regarding culturing pre-cotyledonary pine Embryogenic cells in synchronization medium for from one to two weeks, as recited in step (b) of Claim 1.

Accordingly, because neither of the cited references provides any teaching regarding the synchronization of pre-cotyledonary pine embryogenic cells, and in particular, the cultivation of pre-cotyledonary pine embryogenic cells for a period of one to two weeks in synchronization medium as claimed, the cited references alone or in combination do not teach or suggest every element of Claim 1.

No motivation to modify the teachings of Pullman and/or Gupta to arrive at the claimed invention

There is no suggestion or motivation provided in either Pullman or Gupta to modify the teachings of the cited references, which are both directed to singulation in Douglas-fir, in order

to arrive at the claimed invention, which is directed to synchronization of pine pre-cotyledonary embryos. As noted supra, the step of singulation is carried out during Douglas-fir embryogenesis due to the formation of tight clusters of Douglas-fir embryos. As described in the cited references, the step of singulation in Douglas-fir is carried out for at least three weeks in a series of liquid shake cultures. See Gupta at Col. 8, lines 4-9; and Pullman et al. at Col. 8, lines 18-21. There is no suggestion or motivation provided in either reference to modify the teachings to reduce the time of incubation in singulation medium to 1 to 2 weeks, as claimed, because the proposed modification would likely render the methods of the cited references inoperable, or at least less efficacious, for their intended purpose of singulation.

Moreover, it is further noted that the Examiner admits that neither Pullman nor Gupta teach or remotely suggest synchronization of embryos. As described in the present specification, the claimed invention is based on the discovery by the present inventors that culturing pine embryos in a synchronization medium that comprises maltose as the principle metabolizable sugar source, an absorbent composition (e.g., activated charcoal) and at least one of abscisic acid and a gibberellin for one to two weeks prior to incubation in development media inhibited precocious embryo development and greening, while promoting synchronization of the cultures, thereby resulting in embryos very uniform in size in comparison to control cultures.

Specification at page 19, lines 19-31; page 16, lines 26-30, and Tables 1 and 2. As further described in the instant specification, it was experimentally determined that in the absence of the step of culturing in a synchronization medium (i.e., control cultures grown in maintenance medium and directly transferred to development medium, similar to Examples 8 and 9 of Pullman et al.), the resulting cultures were not synchronized, and contained embryos that were cleaving, growing, and forming embryo suspensor masses, with embryos seen in many different stages. Specification at page 19, lines 1-5.

These arguments are not found persuasive because Pullman et al. teach culturing of proembryos in a maintenance medium then transferring the late proembryos in a singulation medium comprising active gibberellins and abscisic acid and finally transferring these proembryos to an embryo development medium (column 15, lines 5-35). Pullman et al. state that adding the singulation step is beneficial for improvement of proembryo quality (column 8, lines 5-14). Pullman et al. also teach that "for virtually all coniferous species a supply of exogenous abscisic acid is a useful hormone in the development from proembryos to cotyledonary embryos...this was always used in combination with an absorbent such as activated charcoal." (column 9, lines 49-55). Pullman et al. then add that the addition of the combination of Gibberellin and Abscisic acid reduces tendency to precocious germination. The singulation step taught by Pullman et al. is identical to the synchronization step as claimed. Thus, the method taught by Pullman et al. is identical to the present method as it comprises every step of the claimed method, and is presumed to inherently possess the same properties. Pullman et al. teach a singulation step (synchronization) which encompass two or three transfers at weekly intervals, which is one to two weeks as claimed (column 8, line 32). The method described in example 1 is for Douglas-fir embryos but earlier Pullman et al. state: It appears now that the inclusion of between 0.05 and 15 mg/L preferably about 1-5 mg/L of selected active gibberellins and abscisic acid in the late proembryo development media is also beneficial for improvement of proembryo quality...These may then transferred to an embryo development medium...(column 8, lines 4-14). Pullman et al. also clearly state: species other than Douglas-fir can be advantageously cultured by beginning early cotyledonary embryo development in a series of media similar to those used for Douglas-fir singulation.(column 8, lines 49-52). Pullman et al. is silent about the uniformity in size of the embryos obtained but a reference which is silent about a claimed invention's feature is inherently anticipatory if the missing feature is necessarily present in that which is described in the reference. In re Oelrich, 212 USPQ 323 (CCPA 1981). Pullman et al. is silent in the time frame period claimed in step (c) and but the amount of time the embryos are kept on the development medium is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal time the embryos have to be kept on the development medium to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of time would have been obvious at the time of Applicant's invention.

Although none of the references teach that the method used produces 50% or 75% of the embryos population at the same developmental stage produced by the instant method, it would be known that by using known media and other well-known medium additives, it would be obvious that one skilled in

the art would have obtained 50% or 75% of the embryos population at the same developmental stage.

None of the references teach a solid singulation (synchronization) medium but the use of a solid medium is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of time would have been obvious at the time of Applicant's invention.

Pullman et al. fail to teach a singulation (synchronization) medium comprising maltose as the principal sugar source.

However,

Gupta teaches a singulation medium comprising maltose as the principal sugar source.

All of the claimed elements are either found in the prior art or are optimization of parameters. Moreover, Pullman clearly states that optimization "considered to be within the routine experimental capability of those skilled in the art of tissue culture" (Pullman, col.23, lines 8-10). Applicants have not explained why it would not have been obvious, as asserted by the examiner, to optimize the culture conditions to have achieved the claimed subject matter.